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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/866,557	05/24/2001	David Beach	GNCA-P02-007	4804
28120	7590	03/30/2004	EXAMINER	
ROPES & GRAY LLP ONE INTERNATIONAL PLACE BOSTON, MA 02110-2624			WILDER, CYNTHIA B	
			ART UNIT	PAPER NUMBER
			1637	
DATE MAILED: 03/30/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/866,557

Applicant(s)

BEACH ET AL.

Examiner

Cynthia B. Wilder, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,4,9,10 and 12-42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1, 3, 4, 9, 10, and 12-42 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☒ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. The application has been transferred from Examiner Shar Hashemi to Examiner Cynthia Wilder. All further correspondence should be directed to Examiner Cynthia Wilder whose contact information appears at the end of this Office Action.

2. The restriction requirements submitted on July 19, 2002 and March 28, 2003 are not clear on the record. Therefore due to the lack of clarity on the record, both previous restriction requirements are being vacated in lieu of this Office Action. Claims 2, 5-8 and 11 have been canceled. Claims 1, 3, 4, 9, 10, 12-42 are pending and are discussed below.

Election/Restrictions

3. Restriction to one of the following inventions is required under 35 U.S.C. 121:
- I. Claim 1, 3, 4, 9, 10, 12-15 and 26-29, drawn to a method for attenuating expression of a target gene, classified in class 424, subclass 93.2.
 - II. Claim 16, drawn to an assay for identifying nucleic acid sequences, classified in class 435, subclass 7.1.
 - III. Claims 17-19, drawn to a method of conducting a drug discovery business, classified in class 514, subclass 1.
 - IV. Claims 20-22, drawn to a method for attenuating expression of a target gene utilizing a hairpin nucleic acid, classified in class 424, subclass 93.2.
 - V. Claims 23-25, drawn to a transgenic animal, classified in class 800, subclass 3.

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VI. Claims 30-40, drawn to an isolated guide RNA, classified in class 435, subclass 194.

VII. Claims 41 and 42, drawn to a method of generating knockout cells, classified in class 435, subclass 320.1.

4. The inventions are distinct, each from the other because of the following reasons:

Restriction is deemed to be proper because these methods appear to constitute patently distinct inventions for the following reasons: Group I, II, III, IV and VII are directed to methods that are distinct both physically and functionally, and are not required one for the other. Invention I requires the search of methods for attenuating expression utilizing double-stranded RNA whereby a complementary guide nucleotide sequence hybridizes to a portion of a target gene, which is not required by groups II, III, IV and VII. Invention II requires the search of assays for identifying nucleic acid sequence utilizing a library, which is not required by groups I, III, IV and VII. Invention III requires the search of methods for conducting a drug discovery whereby a pharmaceutical composition is formulated, which is not required by groups I, II, IV and VII. Invention IV requires the search of methods for attenuating expression utilizing a hairpin nucleic acid comprising an inverted repeat, which is not required by Groups I-II and VII. Invention VIII requires the search of method for generating knockout cells, which is not required by groups I, II, III and IV. Therefore, a search and examination of all five methods in one patent application would result in an undue burden, since the searches for the five methods are not co-extensive. The classifications of the different inventions are different and the subject matter is divergent.

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5. Inventions VI and I are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the isolated guide RNA of Group VI can be used in a materially different process, such as e.g., RT-PCR or Northern Blot analysis or nucleic acid sequencing procedures.

6. Inventions V and I-IV and VI-VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, Invention V has different function such as the use of transgenic animal models in research procedures to study growth and development or to study pathophysiology. The different inventions are distinct and requires different fields of search.

7. Because these inventions are distinct for the reasons given above and the search required for any one group is not required for the other Groups, restriction for examination purposes as indicated is proper.

8. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

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remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Contact Information

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia B. Wilder, Ph.D. whose telephone number is (571) 272-0791. The examiner works a flexible schedule and can be reached by phone and voice mail. Alternatively, a request for a return telephone call may be emailed to cynthia.wilder@uspto.gov. Since email communications may not be secure, it is suggested that information in such request be limited to name, phone number, and the best time to return the call.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (703) 308-1119. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Cynthia Wilder
CYNTHIA WILDER
PATENT EXAMINER
3/25/2004